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10/590,131

Application Number

Substitute for form 1449/PTO

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Sheet

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of

Filing Date	August 18, 2006	
First Named Inventor	Andrew S. Rice	
Art Unit	N/A	
Examiner Name	Not Yet Assigned	

Attorney Docket Number | 0290897.00124US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

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		FOREIG	GN PATENT	DOCUMENTS		
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
Initials*	No.1	- I	MM-DD-YYYY	Applicant of Cited Document		Ι Το
	ВА	WO-99/26584	06-03-1999	The Scripps Research Institute		
	ВВ	WO-00/32200	11-24-1998	Makriyannis et al.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ¹ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	CA	ABBOTT, F. V. et al., "The formalin test: scoring properties of the first and second phases of the pain response in rats", <i>Pain</i> , Vol. 60, pp. 91-102, 1995	
	СВ	BAKER, D. et al., "Endocannabinoids control spasticity in a multiple sclerosis model", <i>The FASEB Journal</i> , Vol. 15, pp. 300-302, February 2001	
	СС	BEAULIEU, P. et al., "Role of the endogenous cannabinoid system in the formalin test of persistent pain in the rat", <i>European Journal of Pharmacology</i> , Vol. 396, pp. 85-92, 2000	
	CD	BEVAN, S. et al., "Development of a Competitivve Antagonis for the Sensory Neurone Excitant, Capsaicin", <i>Br. J. Pharmacol.</i> , Vol. 102, p. 77p	
	CE	BOGER, D. L. et al., "Arachidonic Acid Amide Inhibitors of Gap Junction Cell-Cell Communication", <i>Bioorganic &amp; Medicinal Chemistry Letters</i> , Vol. 9, pp. 1151-1154, 1999	
	CF	BOGER, D. L. et al., "Chemical requirements for inhibition of gap junction communication by the biologically active lipid oleamide", <i>PNAS</i> , Vol. 95, pp. 4810-4815, April 1998	
	CG	BOGER, D. L. et al., "Exceptionally potent inhibitors of fatty acid amide hydrolase: The enzyme responsible for degradation of endogenous oleamide and anandamide", <i>PNAS</i> , Vol. 97, No. 10, pp. 5044-5049, 9 May 2000	
	СН	BOGER, D. L. et al., "Fatty Acid Amide Hydrolase Substrate Specificity", <i>Bioorganic &amp; Medicinal Chemistry Letters</i> , Vol. 10, pp. 2613-1616, 2000	
	CI	BOGER, D.L. et al., "Structural requirements of 5-HT2A and 5-HT1A serotonin receptor potentiation by the biologically active lipid oleamide", <i>PNAS</i> , Vol. 95, pp. 4102-4107, April 1998	
	C1	BOUABOULA, M. et al., "A Selective Inverse Agonist for Central Cannabinoid Receptor Inhibits Mitogen-activated Protein Kinas Activation Stimulated by Insulin or Insulin-like Growth Factor 1", <i>The Journal of Biological Chemistry</i> , Vol. 272, No. 35, pp. 22330-22339, 29 August 1997	

Examiner	Date
Signature	Considered

Substitute for form 1449/PTO				Complete if Known		
		, •		Application Number	10/590,131	
l II	NFORMATIC	ON DISC	CLOSURE	Filing Date	August 18, 2006	
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Sheet	2	of	5	Attorney Docket Number	0290897.00124US1	

СК	BRIDGES, D. et al., "The synthetic cannabinoid WIN55,212-2 attenuates hyperalgesia and allodynia in a rat model of neuropathic pain", <i>British Journal of Pharmacolocy</i> , Vol. 133, pp. 586-594, 2001	
CL	CALIGNANO, A. et al., "Antinociceptive activity of the endogenous fatty acid amide, palmitylethanoloamide", <i>European Journal of Pharmacology</i> , Vol. 419, pp. 191-198, 2001	
СМ	CALLIGNANO, A. et al., "Control of pain initiation by endogenous cannabinoids", <i>Nature</i> , Vol. 394, pp. 277-281, 16 July 1998	
CN	CARLTON, S. M. et al., "Behavioral manifestations of an experimental model for peripheral neuropathy produced by spinal nerve ligation in the primate", <i>Pain</i> , Vol. 56, pp. 155-166, 1994	
СО	COMPTON, D. R. et al., "The Effect of the Enzyme Inhibitor Phenylmethylsulfony Fluoride on the Pharmacological Effect of Anandamide in the Mouse Model of Cannabimimetic Activity", <i>The Journal of Pharmacology and Experimental Therapeutics,</i> Vol. 283, No. 3, pp. 1138-1143, 1997	
СР	CRAVATT, B. F. et al., "Supersensitivity to anandamide and enhanced endogenous cannabinoid signaling in mice lacking fatty acid amide hydrolase", <i>PNAS</i> , Vol. 98, No. 16, pp. 9371-9376, 31 July 2001	
CQ	D'AMOUR, F. E. et al., "A Method for Determining Loss of Pain Sensation", From the Biologic Research Laboratory, University of Denver, pp. 74-79, 1941	
CR	DALLEL, R. et al., "Evidence for a peripheral origin of the tonic nociceptive response to subcutaneous formalin", <i>Pain</i> , Vol. 61, pp. 11-16, 1995	
cs	DAMAS, J. et al., "The inflammatory reaction induced by formalin in the rat paw", Naunyn-Schmiedeberg's Arch Pharmacol, Vol. 359, pp. 220-227, 1999	
СТ	DAY, T. A. et al., "Role of Fatty Acid Amide Hydrolase in the Transport of the Endogenous Cannabinoid Anandamide", <i>Molecular Pharmacology</i> , Vol. 59, No. 6, pp. 1369-1375, 2001	
CU	DE PETROCELLIS, L. et al., "Palmitoylethanolamide enhances anandamide stimulation of human vanilloid VR1 receptors", FEBS Letters, Vol. 506, pp. 253-256, 2001	
CV	DEUTSCH, D. G. et al., "The Cellular Uptake of Anandamide is Coupled to its Breakdown by Fatty-acid Amide Hydrolase", <i>The Journal of Biological Chemistry</i> , Vol. 276, No. 10, pp. 6967-6973, 9 March 2001	
cw	DICKENSON, A.H. et al., "Selective antagonism of capsaicin by capsazepine: evidence for a spinal receptor site in capsaicin-induced antinociception", <i>Br. J. Pharmacol.</i> , Vol. 104, pp. 1045-1049, 1991	
СХ	DIMARZO, V. et al., "Anandamide: some like it hot", TRENDS in Pharmacological Sciences, Vol. 22, No. 7, July 2001	
CY	DIMARZO, V. et al., "Hypolocomotor effects in rats of capsaicin and two long chain capsaicin homologues", <i>European Journal of Pharmacology</i> , Vol. 420, pp. 123-131, 2001	
CZ	DUBUISSON, D. et al., "The formalin test: A quantitative study of the analgesic effects of morphine, meperidine, and brain stem stimulation in rats and cats", <i>Pain</i> , Vol. 4, pp. 161-174, 1977	
CA1	EGERTOVA, M. et al., "A new perspective on cannabinoid signaling: complementary localization of fatty acid amide hydrolase and the CB1 receptor in rat brain", <i>Proc. R. Soc. Lond.</i> , Vol. 265, pp. 2081-2085, 1998	
CB1	FACCI, L. et al., "Mast Cells Express a Peripheral Cannabinoid Receptor with Differential Sensitivity to Anandamide and Palmitoylethanolamide", <i>Proc. Natl. Acad. Sci.</i> , Vol. 92, pp. 3376-3380, April 1995	
CC1	FARQUHAR-SMITH, W. P. et al., "A Novel Neuroimmunie Mechanism in Cannabinoid-mediated Attenuation of Nerve Growth Factor-induced Hyperalgesia", <i>Anesthesiology</i> , Vol. 99, pp. 1391-19401, 2003	

Examiner	Date	
Signature	 Considered	

Substitute for form 1449/PTO				Complete if Known		
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11	NFORMATIO	N DIS	CLOSURE	Filing Date	August 18, 2006	
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	(Use as many	sheets as r	necessary)	Examiner Name	Not Yet Assigned	
Sheet	3	of	5	Attorney Docket Number	0290897.00124US1	

CD1	FARQUHAR-SMITH, W. P. et al., "Administration of Endocannabinoids Prevents a Referred	
	Hyperalgesia Associated with Inflammation of the Urinary Bladder", <i>Anesthesiology</i> , Vol. 94, pp. 507-513, 2001	
CE1	FARQUHAR-SMITH, W. P. et al., "Attenuation of nerve growth factor-induced visceral hyperalgesia via cannabinoid CB1 and CB2-like receptors", Vol. 97, pp. 11-21, 2002	
CF1	FARQUHAR-SMITH, W. P. et al., "Cannabinoid CB1 Receptor Expression in Rat Spinal Cord", Molecular and Cellular Neuroscience,, Vol. 15, pp. 510-521, 2000	
CG1	HARGREAVES, K. et al., "A new and sensitive method for measuring thermal nociception in cutaneous hyperalgesia", <i>Pain</i> , Vol. 32, pp. 77-88, 1988	-
CH1	HENRY, J. L. et al., "Physiological evidence that the 'interphase' in the formalin test is due to active inhibition", <i>Pain</i> , Vol. 82, pp. 57-63, 1999	
CI1	HILLARD, C. J., "Biochemistry and pharmacology of the endocannabinoids arachidonylethanolamide and 2-arachidonylglycerol", <i>Prostaglandins &amp; other Lipid Mediators</i> , Vol. 61, pp. 3-18, 2000	
CJ1	JACOBSSON, S. O. P. et al., "Characterization of palmitoylethanolamide transport in mouse Neuro-2a neuroblastoma and rat RBL-2H3 basophilic leukemia cells: comparison with anandamide", <i>British Journal of Pharmacology</i> , Vol. 132, pp. 1743-1754, 2001	
CK1	JAGGAR, S. I. et al., "The anti-hyperalgesic actions of the cannabinoid anandamide and the putatiive CB2 receptor agonist palmitoylethanolamide in visceral and somatic inflammatory pain", <i>Pain</i> , Vol. 76, pp. 189-199, 1998	
CL1	JAGGAR, S.I. et al., "The endogenous cannabinoid anandamide, but not the CB2 ligand palmitoylethanolamide, prevents the biscero-visceral hyper-reflexia associated with inflammation of the rat urinary bladder", <i>Neuroscience Letters</i> , Vol. 253, pp. 123-126, 1998	
CM1	JONSSON, K.O. et al., "Effects of homologues and analogues of palmitoylethanolamide upon the inactivation of the endocannabinoid anandamide", <i>British Journal of Pharmacology</i> , Vol. 133, pp. 1263-1275, 2001	i
CN1	KIM, S. H. et al., "An experimental model for peripheral neuropathy produced by segmental spinal nerve ligation in the rat", <i>Pain</i> , Vol. 50, pp. 355-363, 1992	
CO1	KREITZER, A. C. et al., "Retrograde Inhibition of Presynaptic Calcium Influx by Endogenous Cannabinoids at Excitatory Synapses onto Purkinje Cells", <i>Neuron</i> , Vol. 29, pp. 717-727, March 2001	
CP1	LAMBERT, D. M. et al., "Anticonvulsant Activity of <i>N</i> -Palmitoylethanolamide, a Putatiive Endocannabinoid, in Mice", <i>Epilepsia</i> , Vol. 42, No. 3, pp. 321-327, 2001	
CQ1	LAMBERT, D.M. et al., "Analogues and homologues of N-palmitoylethanolamide, a putative endogenous CB2 cannabinoid, as potential ligands for the cannabinoid receptors", Biochimica et Biophysica ACTA, Vol. 1440, pp. 266-274, 1999	
CR1	LEDENT, C. et al., "Unresponsiveness to Cannabinoids and Reduced Addictive Effects of Opiates in CB1 Receptor Knockout Mice", Science, Vol. 283, pp. 401-404, 15 January 1999	
CS1	LEE, I. et al., "Effects of Different Concentrations and Volumes of Formalin on Pain Response in Rats", ACTA Anaesthesiol., Vol. 38, pp. 59-64, 2000	
CT1	LIN, S. et al., "Novel Analogues of Arachidonylethanolamide (Anandamide): Affinities for the CB1 and CB2 Cannabinoid Receptors and Metabolic Stability", <i>J. Med. Chem.</i> , Vol. 41, pp. 5353-5361, 1998	
CU1	MALMBERG, A. B. et al., "Antinociceptive Actions of Spinal Nonsteroidal Anti-Inflammatory Agents on the Formalin Test in the Rat", <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 263, No. 1, pp. 136-146, 1992	
CV1	MARTIN, B. R. et al., "Cannabinoid Properties of Methylfluorophosphonate Analogs", <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 294, No. 3, pp. 1209-1218.	

Examiner	Date
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Su	Substitute for form 1449/PTO			Complete if Known		
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Sheet	4	of	5	Attorney Docket Number	0290897.00124US1	

		2000	Ĺ			
	CW1	MARTIN, B. R. et al., "Cannabinoid Transmission and Pain Perception", Neurobiology of Disease, Vol. 5, pp. 447-461, 1995, Article No. NB980218				
	CX1	MARTINDALE, J. et al., "Inhibition of C-fibre mediated sensory transmission in the rat following intraplantar formalin", Neurosceience Letters, Vol. 316, pp. 33-36, 2001	Į.			
CY1 MASSEY, R. J., "Catalytic antibodies catching on", <i>Nature</i> , Vol. 328, pp. 457-458, 30 1987						
	CZ1	MATSUDA, L. A. et al., "Structure of a cannabinoid receptor and functional expression of the cloned cDNA", <i>Nature</i> , Vol. 346, pp. 561-564, 9 August 1990	L			
	CA2	MCCALL, W.D. et al., "Formalin induces biphasic activity in C-fibers in the rat", <i>Neuroscience Letters</i> , Vol. 208, pp. 45-48, 1996				
	CB2	MCMAHON, S. B. et al., "A model for the study of visceral pain states: chronic inflammation of the chronic decerebrate rat urinary bladder by irritant chemicals", <i>Pain</i> , Vol. 28, pp. 109-124, 1987				
	CC2	MUNRO, S. et al., "Molecular characterization of a peripheral receptor for cannabinoids", Nature, Vol. 365, pp. 61-65, 2 September 1993				
	CD2	NESS, T.J. et al., "Colorectal distension as a noxious visceral stimulus: physiologic and pharmacologic characterization of pseudaffective reflexes in the rat", <i>Brain Research</i> , Vol. 450, pp. 153-169, 1988				
	CE2	PATE, D. W. et al., "Effects of Topical Anandamides on Intraocular Pressure in Normotensive Rabbits", <i>Life Sciences</i> , Vol. 58, No. 21, pp. 1849-1860, 1996				
	CF2					
	CG2					
	CH2	PUIG, S. et al., "Formalin-evoked activity in identified primary afferent fibers: systemic lidocaine suppresses phase-2 activity", <i>Pain</i> , Vol. 64, pp. 345-355, 1995				
	CI2	RICE, A. S. C. et al., "Cannabinoids and Pain", <i>Proceedings of the 10th World Congress on Pain</i> , Vol. 24, pp. 437-468, 2003				
	CJ2	RICE, A.S.C. et al., "Endocannabinoids and pain: spinal and peripheral analgesia in inflammation and neuropathy", <i>Prostaglandins, Leukotrienes and Essential Fatty Acids,</i> Vol. 66, No. 2 & 3, pp. 243-256, 2002				
	CK2	RINALDI-CARMONA, M. et al., "Biochemical and Pharmacological Characterization of SR141716A, the First Potent and Selective Brain Cannabinoid Receptor Antagonist", <i>Life Sciences</i> , Vol. 56, No. 23/24, pp. 1941-1947, 1995				
	CL2	RINALDI-CARMONA, M. et al., "SR 144528, the First Potent and Selective Antagonist of the CB 2 Cannabinoid Receptor", <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 284, No. 2, pp. 644-650, 1998				
CM2 ROMERO, J. et al., "Fatty acid amide hydrolase localization in the human central nervous system: an immunohistochemical study", <i>Molecular Brain Research</i> , Vol. 100, pp. 85-93, 2						
	CN2 ROSLAND, J. H., "The formalin test in mice: the influence of ambient temperature", <i>Pain</i> , Vo 45, pp. 211-216, 1991					
	CO2	SELTZER, Z. et al., "A novel behavioral model of neuropathic pain disorders produced in rats by partial sciatic nerve injury", <i>Pain</i> , Vol. 43, pp. 205-218, 1990				
	CP2	SENTER, P. D. et al., "Activation of Prodrugs by Antibody-Enzyme Conjugates", Immunobiology of Proteins and Peptides VI, pp. 97-105, 1991	Γ			
	CQ2	SENTER, P. D. et al., "Generation of Cytotoxic Agents by Targeted Enzymes", <i>Bioconjugate Chem.</i> , Vol. 4, pp. 3-9, 1993				
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Sub	estitute for form 1449/PTO		-	Complete if Known	
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	(Use as many sh	eets as	s necessary)	Examiner Name	Not Yet Assigned
Sheet	5	of	5	Attorney Docket Number	0290897.00124US1

CR2	SMART, D. et al., "THe endogenous lipid anandamide is a full agonist at the human vanilloid receptor (hVR1)", <i>British Journal of Pharmacology</i> , Vol. 129, pp. 227-230, 2000	
CS2	STELLA, V. J. et al., "Prodrugs: A chemical approach to targeted drug delivery", <i>Prodrugs</i> , pp. 247-267	
CT2	STRANGMAN, N.M. et al., "Evidence for a role of endogenous cannabinoids in the modulation of acute and tonic pain sensitivity", <i>Brain Research</i> , Vol. 813, pp. 323-328, 1998	
CU2	TIGER, G. et al., "Pharmacological Properties of Rat Brain Fatty Acid Amidohydrolase in Different Subcellular Fractions Using Palmitoylethanolamide as Substrate", <i>Biochemical Pharmacology</i> , Vol. 59, pp. 647-653, 2000	
CV2	TSOU, K. et al., "Fatty acid amide hydrolase is located preferantially in large neurons in the rat cnetral nervous system as revealed by immunohistochemistry", <i>Neuroscience Letters</i> , Vol. 254, pp. 137-140, 1998	
CW2	UEDA, N. et al., "The fatty acid amide hydrolase (FAAH)", Chemistry and Physics of Lipds, Vol. 108, pp 107-121, 2000	
CX2	URBAN, L. et al., "Capsazepine, a novel capsaicin antagonist, selectively antagonises the effects of capsaicin in the mouse spinal cord in vitro", <i>Neuroscience Letters</i> , Vol. 134, pp. 9-11, 1991	
CY2	VANDEVOORDE, S. et al., "Modifications of the Ethanolamine Head in N-Palmitoylethanolamine: Synthesis and Evaluation of New Agents Interfering with the Metabolism of Anandamide", J. Med. Chem., Vol. 46, pp. 1440-1448, 2003	
CZ2	WALKER, J. M. et al., "Pain modulation by release of the endogenous cannabinoid anandamide", <i>PNAS</i> , Vol. 96, No. 21, pp. 12198-12203, 12 October 1999	
CA3	WATSON, G. S. et al., "Optimal scoring strategies and weights for the formalin test in rats", Pain, Vol. 70, pp. 53-58, 1997	
СВЗ	WILMAN, D. E. V., "Prodrugs in cancer chemotherapy", Action Cancer Guest Lecuture, 615th Meeting, Belfast, Vol. 14, pp. 375-382, 1986	
CC3	YAMADA, K. et al., "Stress-induced behavioral responses and multiple opioid systems in the brain", <i>Behavioural Brain Research</i> , Vol. 67, pp. 133-145, 1995	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 6,09. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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